

Atty E. 1397.002
2302-1397
PATENT

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8/7/98
Date

Patricia K. Roman
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

O'Hagan et al.

Serial No.: 09/015,736

Group Art Unit: Unassigned

Filing Date: January 29, 1998

Examiner: Unassigned

Title: USE OF MICROPARTICLES COMBINED WITH SUBMICRON OIL-IN-WATER EMULSIONS

CERTIFICATION UNDER 37 C.F.R. § 1.97(e)(1)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The undersigned hereby certifies that each item of information contained in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

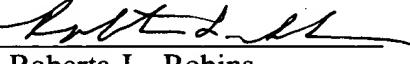
RECEIVED

Respectfully submitted,

AUG 11 1998

Date: 8/7/98

CUSTOMER
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By:


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Atty. No. 1397.002
Client No. 2302-1397
PATENT

EDU 1643

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In Re Application of:

AUG 11 1998

O'Hagan et al.

MAILED COURIER

Serial No.: 09/015,736

Group Art Unit: Unassigned SERVICE CENTER

Filing Date: January 29, 1998

Examiner: Unassigned

Title: USE OF MICROPARTICLES COMBINED WITH SUBMICRON OIL-IN-WATER EMULSIONS

TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is an Information Disclosure Statement, including a Form PTO-1449 and copies of the cited references. It is believed that no fee is due.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 8/7/98

By: Roberta L. Robins
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#4/JR
10/16/98

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on August 7, 1998.

8/7/98
Date

Patricia K. James
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

O'HAGAN et al.

Serial No.: 09/015,736

Group Art Unit: Unassigned

Filing Date: January 29, 1998

Examiner: Unassigned

Title: USE OF MICROPARTICLES COMBINED WITH SUBMICRON OIL-IN-WATER EMULSION

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

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Assistant Commissioner for Patents
Washington, D.C. 20231

AUG 11 1998
MAILED CUSTOMER
SERVICE CENTER

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

United States Patent No. 5,629,167 issued May 13, 1997 to Ratti;
International Patent No. WO 90/14837, published December 13, 1990;
International Patent No. WO 92/00081, published January 9, 1992;
International Patent No. WO 97/02810, published January 30, 1997;
European Publication No. EP 0 399 843 B1, published July 13, 1994;

A.S. Fauci, "Update on the Status of Vaccine Development," *Pediatric Aids and HIV Infection: Fetus to Adolescent* 5(1):47-58 (1994);

Higgins et al., "MF59 Adjuvant Enhances the Immunogenicity of Influenza Vaccine in Both Young and Old Mice," *Vaccine* 14(6):478-484 (1996);

Moore et al., "Immunization with a Soluble Recombinant HIV Protein Entrapped in Biodegradable Microparticles Induces HIV-Specific CD8⁺ Cytotoxic T Lymphocytes and CD4⁺ Th1 Cells," *Vaccine* 13(18):1741-1749 (1995);

O'Hagan et al., "Biodegradable Microparticles for Oral Immunization," *Vaccine* 11:149-154 (1993);

O'Hagan, "Recent Advances in Vaccine Adjuvants for Systemic and Mucosal Administration," *J. Pharm. Pharmacol.* 49:1-10 (1997);

Ott et al., "Design and Evaluation of a Safe and Potent Adjuvant for Human Vaccines," *Vaccine Design: The Subunit and Adjuvant Approach* (Powell, M.F. and Newman, M.J. eds.) Plenum Press, New York, pp. 277-296 (1995);

Sanchez-Pescador et al., "The Effect of Adjuvants on the Efficacy of a Recombinant Herpes Simplex Virus Glycoprotein Vaccine," *The Journal of Immunol.* 141(5):1720-1727 (1988); and

Vordermeier et al., "Synthetic Delivery System for Tuberculosis Vaccines: Immunological Evaluation of the *M. Tuberculosis* 38 kDa Protein Entrapped in Biodegradable PLG Microparticles," *Vaccine* 13(16):1576-1582 (1995).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

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(iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 8/7/98

By: Roberta L. Robins

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